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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/539,723 | 06/20/2005 | Michaela Hochne | 65084.000013 | 5109 |
| 21967 7590 04/29/2009 HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109 | | | | |
| EXAMINER | | | | |
| PAGE, BRENT T | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1638 | | | | |
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| 04/29/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,723

Applicant(s)

HOEHNE ET AL.

Examiner

BRENT PAGE

Art Unit

1638

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-28, 30, 32-50 and 52 is/are rejected.
- 7) ☒ Claim(s) 29, 31, 51 and 53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date 2/2009
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/03/2009 has been entered. The addition of new claims 42-53 is hereby acknowledged. Claims 22-53 are pending and examined herein on the merits.

Specification

The disclosure is objected to because of the following informalities: Page 61 of the specification recites sequences without SEQ ID NOs. A complete sequence listing must be provided.

Appropriate correction is required.

Claim Rejections - 35 USC § 112-enablement

Claims 22-28, 30, 32-50, and 52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the suppression of SSIII, BEI, and BEII with antisense sequences comprising at least 95% of SEQ ID NOs 1, 4, and 6, respectively, does not reasonably provide enablement for cosuppression molecules or duplex RNA molecules that suppress SSIII, BEI and BEII. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims remain rejected for the reasons of record in the office actions mailed out 03/07/2007 and 08/28/2008 as well as the reasons set forth below.

Applicant's arguments filed 03/26/2009 have been fully considered but they are not persuasive.

Applicants urge that the claim amendments obviate the rejections of record and that methods of suppressing gene expression are well known in the art (See page 18 of response and page 11-12 of previous response).

This is not persuasive because the specification does not give guidance for co-suppression and duplex RNA gene suppression for any of the sequences of the instant invention. Particularly wherein 95% identity to a genomic sequence is claimed in relation to a cosuppression molecule, which may encompass the entire reading frame of the resultant polypeptide and may in fact overexpress, rather than silence expression. Co-suppression resulting from the expression of the full length transcript is rare and unpredictable.

In a review of gene silencing Vaucheret et al (2001 Trends in Genetics 17:29-35) disclose that number of factors determine whether or not cosuppression takes place by introducing a transgene such as copy number and the gene being silenced (see page 29, second column, for example). Without a single example demonstrating co-suppression of the gene of interest, it remains unpredictable the effect that the transgene will have on gene expression. Furthermore, regarding claims 42-49, 15

nucleotides would not be sufficient to perform antisense, particularly wherein the poly-A tail is 14 nucleotides long and with only 1 additional nucleotide is encompassed by the claims.

Given the state of the art, the disclosure by Vaucheret et al, and the unpredictability as discussed above, it would be undue experimentation for one of skill in the art to evaluate all sense molecules with 95% or greater identity to the transgene to determine if co-suppression takes place. Accordingly, the claims are not enabled over the full scope.

Claim Rejections - 35 USC § 112-written description

Claims 22-28, 30, 32-50, and 52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims remain rejected for the reasons of record in the office actions mailed out 03/07/2007 and 08/28/2008 as well as the reasons set forth below.

Applicant's arguments filed 03/26/2009 have been fully considered but they are not persuasive.

Applicants urge that the claim amendments obviate the rejections of record and that methods of suppressing gene expression are well known in the art (See page 18 of response and page 11-12 of previous response).

This is not persuasive because the specification does not disclose a single working example for co-suppression of any of the transgenes claimed by the instant invention. Without a description of even a single working embodiment, it is not possible to then describe the necessary structures required for the function of co-suppression, and therefore the claims lack written description for co-suppression silencing of the genes. Additionally, the specification does not describe molecules as small as 15 nucleotides of the specified sequences that function as co-suppression, antisense, or duplex RNA silencing molecules.

Claims 29, 31, 51 and 53 are objected to for depending on rejected claims but would be allowable if rewritten in independent form.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phuong T. Bui/
Primary Examiner, Art Unit 1638

Brent T Page